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| 10/004,118 | 10/30/2001 | Stanford Mark Moran | BMED-004/01US | 8022 |
| 23419 | 7590 | 12/15/2004 | EXAMINER | |
| COOLEY GODWARD, LLP 3000 EL CAMINO REAL 5 PALO ALTO SQUARE PALO ALTO, CA 94306 | | | ANDRES, JANET L | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1646 | |

DATE MAILED: 12/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/004,118

Applicant(s)

MORAN, STANFORD MARK

Examiner

Janet L. Andres

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 September 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-17, 19, 20, 22, 24-38, 40-54 and 68-77 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-17, 19, 20, 22, 24-38, 40-54, 68-77 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

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RESPONSE TO AMENDMENT

1. Applicant's amendment filed 20 September 2004 is acknowledged. Claims 2-17, 19, 20, 22, 24-38, 40-54, and new claims 68-77 are pending and under examination in this office action. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior office action.

Claim Rejections Maintained

2. The rejection of claims 2, 3, 8, 10, 14-17, 19, 22, 24, 28, 30, 34-38, and 40-54 under 35 U.S.C. 103(a) as unpatentable over Sorenson in view of Palmeri and Harper is maintained for reasons of record in the office action of 18 March 2004 and applied to new claims 68- 73.

Applicant argues that Sorenson teaches an external, iontophoretic pump and is thus non-analogous art. Applicant states that Sorenson does not teach a method that uses an internally presented implantable pump that is not externally programmed". Applicant states that the method of Sorenson is intended to provide the patient with an initial high peak level of drug, followed by lower maintenance levels, while the purpose of Applicant's short-term formulation, while a high peak level may exist, is fine-tuning. Applicant states that the reference should be in the field of the inventor's endeavor or reasonably pertinent, while Sorenson's pump is so different as to not fall within the field of endeavor. Applicant argues that Sorenson discloses a very different device for a very different purpose. Applicant additionally argues that Harper does not provide the necessary motivation to combine the references and that it does not teach a method of administering and adjusting the steps. Applicant argues that Palmeri does not provide the suggestion to combine the references and further that the combination of the three references does not lead to Applicant's invention, but rather to two types of pump and an advanced

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colorectal carcinoma optimization study. Applicant concludes that the artisan would not look at Sorenson and combine it with the other teachings and that such combination would not teach or suggest every limitation of the instant claims.

Applicant's arguments have been fully considered but have not been found to be persuasive. In response to applicant's argument that Sorenson is nonanalogous art, Sorenson was not cited as teaching the same sort of pump used in Applicant's methods, but rather, as was stated on p. 3 of the office action of 18 March 2004, was cited as teaching a method of achieving optimal drug levels, including interferons, which is also Applicant's goal. The art is therefore analogous. Harper is cited as teaching the same sort of pump used by Applicant and Applicant has not argued that the pump taught by Harper is different. Harper need not teach a method of administering and adjusting the steps; such a method is taught by Sorenson. One cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In response to applicant's argument that there is no motivation provided by Harper or Palmeri to combine the references, as was stated in the previous office action, Palmeri teaches a problem that can be solved by the method of Sorenson and Harper teaches pumps that are useful for that method. Thus it would be obvious to the artisan of ordinary skill to combine them, resulting not in merely the combination of two pumps and a study but in a method of altering drug levels to optimize doses by administering a first formulation followed by a second formulation using an internal pump. Applicant's amendment removing the specific motivation provided by Palmeri does not render the invention non-obvious; Palmeri is certainly increasing "therapeutic responsiveness" by

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optimizing interferon doses so that the drug can be tolerated. Furthermore, the courts have held that:

Specific statements in the references themselves which would spell out the claimed invention are not necessary to show obviousness, since questions of obviousness involves not only what references expressly teach, but what they would collectively suggest to one of ordinary skill in the art. See CTS Corp. v. Electro Materials Corp. of America 202 USPQ 22 (DC SNY 1979); and In re Burckel 201 USPQ 67 (CCPA 1979).

and

In considering the disclosure of a reference, it is proper to take into account not only specific teaching of the reference but also the inferences which one skilled in the art would be reasonably be expected to draw therefrom In re Preda, 401 F.2d 825, 159 USPQ 342, 344 (CCPA 1968).

and

it is not necessary that the claimed invention be expressly suggested in any one or all of the references to justify combining their teachings; rather the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

Sorenson teaches a method of optimizing interferon doses in which a first level and then a second level is given. Palmeri teaches a need for such optimization and Harper teaches a pump that is useful for such optimization. The combination of Sorenson, Palmeri, and Harper suggests to the artisan of ordinary skill a method of treatment that optimizes interferon doses by administering a first level and then administering a second level, using an internal pump.

New claims 74-77 are drawn to methods using a plurality of animals. As was stated on p. 4 of the office action of 14 July 2003 and again on p. 5 of the office action of 18 March 2004, Palmeri teaches groups of patients and the need for optimization.

3. The rejection of claims 4-7, 9, 12, 13, 20, 25-27, 29, 32, and 33 under 35 U.S.C. 103(a)

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as unpatentable over Sorenson in view of Palmeri and Harper and further in view of Johnson is maintained for reasons of record in the office action of 18 March 2004.

Applicant argues that Johnson fails to overcome the deficiencies of the other references and further argues that “one making the combination... would not have the benefit of the hindsight provided by Applicant’s disclosure and would not arrive at the methods of independent claims 68, 74, and 41”.

Applicant’s arguments have been fully considered but have not been found to be persuasive. For the reasons set forth above, the combination of Sorenson, Palmeri, and Harper would lead the artisan of ordinary skill to Applicant’s invention. Johnson teaches the diseases and interferons within the scope of the claims and further teaches a need for optimization (see p. 4 of the office action of 18 March 2004). No hindsight reasoning is required to apply the method suggested by Sorenson, Palmeri, and Harper to the diseases taught by Johnson; the motivation is provided by Johnson.

4. The rejection of claims 11 and 31 under 35 U.S.C. 103(a) as unpatentable over Sorenson in view of Palmeri, Harper, and Johnson and further in view of Kwan is maintained for reasons of record in the office action of 18 March 2004.

Applicant argues that the disclosure of Kwan fails to address the shortfalls of the other references and further that Kwan provides no motivation to combine the disclosed formulation with Sorenson, Harper, and Palmeri.

Applicant’s arguments have been fully considered but have not been found to be persuasive. For the reasons set forth above, there are no shortfalls in the combination of the other references. Kwan was cited as teaching compositions with advantageous formulations; it

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would be *prima facie* obvious to the artisan of ordinary skill to use them because they are in fact advantageous: they retard microbial growth.

Applicant concludes that the primary reference is arguably from a non-analogous field, that impermissible hindsight is required, and that the references combined do not teach or suggest every limitation of the claims. For the reasons set forth in paragraphs 2-4 above and in the office action of 18 March 2004, Applicant's arguments have not been found to be persuasive. Sorenson teaches a method of optimizing dosage levels of interferon and is not relied upon to teach the instantly claimed pump. No hindsight is required because Palmeri and Johnson both teach the need for optimization. As was discussed in paragraph 2 above and on p. 3 of the office action of 18 March 2004, the combined references do suggest every limitation of the claims.

NO CLAIM IS ALLOWED.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Andres whose telephone number is 571-272-0867. The examiner can normally be reached on Monday, Tuesday, Thursday, Friday, 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Janet L. Andres, Ph.D.
10 December 2004



JANET ANDRES
PRIMARY EXAMINER